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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/484,886

01/18/2000

Gale E. Smith

674506-2035.2

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99562

7590

03/04/2011

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

03/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/484,886	Applicant(s) SMITH ET AL.	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 153-170 is/are pending in the application.
- 4a) Of the above claim(s) 153-169 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 170 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. By virtue of petition decision from the Director of Technology Center 1600 mailed 30 September 2010, the finality of Office Action mailed 12 March 2010 has been vacated and the status updated to response to Non-final Office action. The following Office Action is issued.
2. Accordingly, the Advisory action mailed 26 August 2010 is also hereby vacated.
3. The response and amendment to Claims filed 09 August 2010 is therefore acknowledged and entered.
4. Also acknowledged and entered is Applicants' Supplemental amendment filed 25 October 2010.
5. Examiner regrets any inconvenience because of delays in issuing the following Office Action.

Claims Status

6. According to the Supplemental amendment filed 25 October 2010, following is the Claims status:

- ⌚ Claims 1-152 are cancelled;
- ⌚ Claim 170 is added; and
- ⌚ Claims 153-170 are pending.

Withdrawn by Original Presentation

7. Newly submitted claims 153-169 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 153-169 recite subject matter drawn to claims non-elected in the Response filed 12 December 2002 electing invention Group IV encompassing Claim 90 drawn to “erythropoietin as the expressed product”. This Election was made in response to Election

Restriction mailed 17 October 2002. The Restriction Election was subsequently made Final in the Office Action mailed 25 March 2003.

Since applicants have received many actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 153-169 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

8. Claim 170 is examined on merits.

Claim Rejections - 35 U.S.C. §112

35 U.S.C. 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claim 170 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ♦ Claim 170 improperly depends from withdrawn Claims. Appropriate correction is required.

Claim Rejections - 35 U.S.C. §102(b)

11. The following is a quotation of 35 U.S.C. §102 which forms the basis for all anticipation rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 170 is rejected under 35 U.S.C. §102(b)/103 as anticipated by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657).

The limitation in Claim 170 is to a substantially pure, recombinant erythropoietin prepared by processes of non-elected claims.

Regarding Claim 170, Quelle et al. teach a glycosylated, >99% pure, recombinant human erythropoietin produced by a baculovirus expression system, said expression system cultured in a SF9 insect cell (Page 652, Column 1, Lines 6-25 and Column 2, Lines 6-13) that retains **some** in vivo activity. Applicants have not demonstrated that the recombinant human erythropoietin produced by a baculovirus expression system, said expression system cultured in a SF900+ insect cell is patentably distinct from that disclosed by Quelle et al. This is a product by process claim, albeit the process steps have been withdrawn from consideration. It is applicants' responsibility to demonstrate that the product produced by their process is patentably distinct from the product produced by the process of the prior art reference, when, as in this case sufficient evidence has been marshaled (in previous actions) to establish that the properties of the product produced by the two processes appear to be the same or at the very least such small and limited differences that the two products are not patentably distinct.

Therefore, the reference is deemed to anticipate or render obvious the cited claim.

Conclusion

13. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. For reasons aforementioned, no Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/JON P WEBER/
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